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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/561,839

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Mordechai Deutsch

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EXAMINER

EDWARDS, LYDIA E

ART UNIT

PAPER NUMBER

1774

MAIL DATE

DELIVERY MODE

03/16/2011

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/561,839	<b>Applicant(s)</b> DEUTSCH ET AL.	
	<b>Examiner</b> LYDIA EDWARDS	<b>Art Unit</b> 1774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Disposition of Claims: Claims pending in the application are 1-  
3,6,7,12,18,22,27,29,42,43,48,49,56,68,86,90,91,121,130,132,139,145,153,178,179,181,186 and 193-214.

Continuation of Disposition of Claims: Claims rejected are 1-  
3,6,7,12,18,22,27,29,42,43,48,49,56,68,86,90,91,121,130,132,139,145,153,178,179,181,186 and 193-214.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :2/27/2011,  
2/16/2011, 2/10/2011, 2/10/2011, 2/6/2011, 2/1/2011, 12/22/2010, 12/20/2010, 11/11/2010, 11/2/2010, 10/31/2010,  
10/25/2010, 10/12/2010, 9/22/2010, 9/22/2010, 9/19/2010, 9/12/2010, 8/30/2010, 8/25/2010.

## **DETAILED ACTION**

### **Continued Examination Under 37 CFR 1.114**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/16/2010 has been entered.

### **Response to Arguments**

Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

Claim objections of Claims 22 and 27 have been withdrawn.

### **Double Patenting**

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 199 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 195. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim

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to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

### **Claim Rejections - 35 USC § 112**

Claims 43, 48 and 214 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding Claims 43 and 214, applicant has failed to define via the specifications and/or disclose via the drawings as to what and how the interwell area between two said wells defines the well structure. Applicant has referred to descriptions in the specification; however, those descriptions merely mention that the interwell area is substantially zero and does not define interwell area.

Regarding Claim 48, applicant has failed to define via the specifications and/or disclose via the drawings as to what and how knife-edge defines the well structure. Applicant has referred to descriptions in the specification; however, those descriptions merely mention that the wells are substantially knife-edged and do not define knife-edged.

Claims 195 and 197-199 are rejected under 35 U.S.C. 112, fourth paragraph, as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claims 195 and 197-199 refer to a method of making and fail to further limit the structure of claim 1.

### **Claim Rejections - 35 USC § 103**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3, 6-7, 35, 42-43, 49, 56, 68, 86, 121, 130, 132, 139, 145, 186 and 193-197, 199-209 and 214 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (US 20030030184) in view of Bochner et al. (US 5627045) in light of Alberte et al. (US 20020052003).

Regarding Claims 1, 35, 42, 56, 86, 145, 195, 197, 200-201, 203-209 Kim et al. ('184) teaches a device for holding living cells, the device comprising a carrier [100] having a plurality of juxtaposed wells [170] disposed on a surface [140] each well configured to hold at least one living cell (Paragraphs 135 and 215 and Figures 1). Kim et al. does not specifically state wherein said wells prevent loss or migration of cells during storage, movement, testing and observation, and inhibit or delay adhesion of living cells thereto.

However, Kim discloses wherein the cells are allowed to attach to the support (surface) [140] and to grow to confluence. The walls of the micro-orifice [300] constrain the cell(s) and the cells take on the shape of the micro-orifice [300], e.g., circular. A test agent is applied through the micro-orifices [300] and is allowed to contact the cells. The first layer (surface) [150] is removed and the cells are observed. If the test agent affects cell movement, the cell will be "stuck" in place as-it was patterned and-may not change shape, i.e., it will remain circular if the patterning member had circular orifices.

Bochner et al. ('045) teaches a method of manipulating cells, comprising: providing a plurality of wells of a well-bearing component, each well configured to hold at least one living cell; holding a plurality of living cells in a plurality of said wells; placing a gellable fluid including but not limited to alginate (Col 8, lines 41-42), in proximity with said surface so as to fill said plurality of wells; and gelling said gellable fluid so as to form a gel cover (Col 8, line 65-Col 9, line 34).

The examiner interprets the gel matrix of Bochner to be a cover once produced, trapping the suspended microorganisms.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Kim with the gelling agents as taught by Bochner et al. in order to provide a testing system that does not spill from the microplate, even if the microplate was inverted therefore, preventing loss or migration of cells during storage, movement, testing and

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observation. Moreover, it allows a novice to work with bacteria and study their biochemical characteristics with a reduced chance of contamination.

Kim et al. does not specifically state wherein the entire interior of the well inhibits adhesion of living cells. However, he does disclose wherein the first layer [150] comprising the walls of each micro-well [150a] of the micro-orifice [300] may be treated, conditioned or coated with a substance that resists cell attachment (Paragraph 139). The flat bottom (See Figures 1c, 8c, 10c, and 11c) of each micro-well [140a] on the upper surface of the support [140] is treated with coating [220] which may be made of any substance that achieves a desired effect on the cells to be arrayed or may be made of any substance to assist in the arraying of the cells or it may be a bio-inert coating (Paragraphs 155 and 198). Kim et al. is silent towards the second layer [160] being treated with a coating. The examiner interprets the bio-inert material of Kim et al. to be equivalent to a substance that resists cell attachment.

However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to treat, condition, or coat the entire microwell with a substance that resists cell attachment to reduce the risk of damaging cells when the first and second layers need to be separated from each other and/or the support. As further evidenced by Alberte et al. it was well known in the art at the time of the invention to use of a compound or composition in a method for inhibiting bioadhesion to a surface of a laboratory apparatus (Abstract, Paragraphs 115 and 118).

Regarding Claims 35 and 56, 195, 197, with respect to the intended use limitations, the device disclosed by the combination of Kim et al. and Alberte et al. as disclosed above is structurally the same as the instantly claimed and is capable of providing the operating conditions listed in the intended use section of the claim. Note statements of intended use carry no patentable weight when the structure of the Claim has been met by the prior art reference.

Regarding Claims 2-3 and 202, Kim et al. ('184) teaches wherein said carrier is substantially made of a material selected from the group consisting of a polydimethylsiloxane, an elastomer and silicon rubber (Paragraphs 138 and 143).

Regarding Claims 6-7, Kim et al. ('184) teaches wherein the carrier can be formed by molding (Paragraph 194). Therefor the device is capable of deforming in at least one dimension and changing the size of the wells.

Regarding Claims 43, 49 and 214, Kim et al. ('184) teaches wherein the dimensions of said wells are less than about 200 microns (Paragraph 142).

Regarding Claim 68, Kim et al. ('184) teaches protuberances protruding from said surface between two adjacent wells (Paragraph 135; Figures 1b:160a; 1b:150a). As interpreted by the examiner, Figure 1b discloses protuberances [150 and 160].

Regarding Claims 121, 130, 132, 139, Kim et al. ('184) teaches a method of making a chip-device of claim 1 comprising: providing a template having a negative of features of said surface of said carrier; contacting said template with a precursor material so as to create said features in said precursor material; and fixing said features in said precursor material so as to fashion said carrier (Paragraphs 190-199 and Figures 9a, 9b, 10a through 10c and 11a through 11c).

PDMS is viscoelastic, meaning that at long flow times (or high temperatures), it acts like a viscous liquid, similar to honey (of which the examiner interprets to be the same as a gellable fluid) which can flow to cover the surface and mold to any surface imperfections. However at short flow times (or low temperatures) it acts like an elastic solid, similar to rubber.

Regarding Claim 186, Kim et al. ('184) teaches a method of growing cells comprising: providing a well-bearing device; holding at least one living cell in a well of said well-bearing device (Figure 1); and increasing the size of said well so as to provide an increased space for proliferation of said cell (Paragraph 208). Kim et al. teaches first layer [150] comprising micro-orifices [300] and second layer [160] comprising macro-orifices [170] (See Figure 7a through 7c).



Regarding Claim 193, the rejection of claim 1 above is relied upon.

Kim et al. ('184) teaches a method comprising: providing a well-bearing device, said well-bearing device having: a plurality of wells disposed on a surface, each well configured to hold at least one cell; and a plurality of protuberances protruding from said surface contacting the biological sample with said surface so as to remove cells from the biological sample (Paragraphs 135, 208 and Figures 1 and 1b). Kim et al. teaches protuberances protruding from said surface between two adjacent wells (Paragraph 135; Figures 1b:160a; 1b:150a). As interpreted by the examiner, Figure 1b discloses protuberances [150 and 160].

Regarding Claim 194, Kim et al. ('184) teaches wherein said wells are formed in said surface (See Figures 9a, 9b, 10a through 10c and 11a through 11c).

Regarding Claim 196, Kim et al. ('184) teaches the micro-orifices 300 of the first layer 150 may have any other arrangement that would be within the knowledge of a person skilled in the art, such as, for example, a rectangular, hexagonal, circular or any another arrangement (Paragraph 140).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to design a well with a rectangular cross-section, since it has been held to be within the general skill of a worker in the art to select a known shape and or orientation on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claims 12, 90-91, and 198 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (US 20030030184) in view of Bochner et al. (US 5627045) in light of Alberte et al. (US 20020052003) as applied above to claim 1, further in light of Sanghera et al. (US 5525800) and Hahn et al. (US 20030017079).

The rejection of claim 1 above is relied upon.

Regarding Claims 12 and 90, Kim et al. ('184) teaches a chip-device for holding living cells, the device comprising a carrier [100] having a plurality of wells [170] disposed on a surface each well configured to hold at least one living cell, the device characterized in that said carrier is made of PDMS, a material having an index of refraction similar to that of water (Paragraphs 138 and 143).

PDMS is well known on the art to have a refractive index of about 1.4 as evidenced by Sanghera et al. in Col 8, lines 54-56 which is close to the refractive index of water which is equal to 1.33 as evidenced by Hahn et al. in Paragraph 19.

Regarding Claim 91 Kim et al. ('184) teaches a chip-device for holding living cells, the device comprising a carrier [100] having a plurality of wells [170] disposed on a surface each well configured to hold at least one living cell, the device characterized in that said carrier is made of a material having an index of refraction similar to that of water (Paragraphs 138 and 143).

PDMS is well known on the art to have a refractive index of about 1.4 as evidenced by Sanghera et al. in Col 8, lines 54-56 which is close to the refractive index of water which is equal to 1.33 as evidenced by Hahn et al. in Paragraph 19.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Kim with a material having an index of refraction less than about 1.4, in order to optimize the carriers ability to identify the particular living cell, confirm its purity or measure its concentration via the use of an optical system.

Regarding Claim 198 with respect to the intended use limitations, the device disclose by the combination of Kim et al., Alberte et al., Sanghera et al. , and Hahn et al. as disclosed above is structurally the same as the instantly claimed and is capable of providing the operating conditions listed in the intended use section of the claim. Note statements of intended use carry no patentable weight when the structure of the Claim has been met by the prior art reference.

Claims 18, 22, 27, 29, 153, 178-179, and 181 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (US 20030030184) in view of Bochner et al. (US 5627045) in light of Alberte et al. (US 20020052003) as applied above to claim 1, further in view Ravkin et al. (US 2003/0059764).

The rejection of claim 1 above is relied upon.

Regarding Claims 18, 22, 27, 29, and 153, Kim et al. ('184) teaches the device of claim 1 except for wherein the carrier and cover are made of gel; placing a gellable fluid in proximity with said surface so as to fill said wells and gelling said gellable fluid so as to form a gel cover.

Bochner et al. ('045) teaches a method of manipulating cells, comprising: providing a plurality of wells of a well-bearing component, each well configured to hold at least one living cell; holding a plurality of living cells in a plurality of said wells; placing a gellable fluid in proximity with said surface so as to fill said plurality of wells; and gelling said gellable fluid so as to form a gel cover (Col 8, line 65-Col 9, line 34).

The examiner interprets the gel matrix of Bochner to be a cover once produced, trapping the suspended microorganisms.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Kim with the gelling agents as taught by Bochner et al. in order to provide a testing system that does not spill from the microplate, even if the microplate was inverted and allows novice to work with bacteria and study their biochemical characteristics with a reduced chance of contamination.

Ravkin ('764) teaches a cell analysis system wherein carriers or portions thereof, such as an outer layer (cover) or an internal region also may be made from a gel (Paragraph 90).

The examiner interprets the outer layer described by Ravkin to be equivalent to a cover.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Kim with gel portion as taught by Ravkin in order to provide a suitable adhesion layer for cells and cell analysis materials or provide a better storage or handling characteristics.

With respect to the intended use limitations, the device disclosed by the combination Kim Alberte et al., Bochner et al. and Ravkin is structurally the same as the instantly claimed and is

capable of providing the operating conditions listed in the intended use section of the claim. Note statements of intended use carry no patentable weight when the structure of the Claim has been met by the prior art reference.

Regarding Claims 178-179 and 181, Kim ('184) teaches contacting an active entity-containing fluid with the well bearing device (Paragraph 205, 208 and 214). Kim also teaches wherein the cells were removed from the macro-wells (Paragraph 293).

Claims 210-213 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (US 20030030184) in view of Bochner et al. (US 5627045) in light of Alberte et al. (US 20020052003) as disclosed above in claim 207, further in view of Oldenburg et al. (US 6027695).

Regarding Claims 210-212, Kim et al., Bochner et al. and Alberte et al. do not disclose the use of vapor deposition.

However, Kim et al. ('184) does teach gelling wherein the gel-forming matrix is in liquid form, allowing for easy dispensing of the suspension into the compartments. These compartments contain dried biochemicals and cations. Upon contact of the gel-forming matrix with the cations, the suspension solidifies to form a soft gel (Col 9, lines 2-6).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the coating by vapor deposition since chemical vapor deposition was well known in the art that as evidence by Oldenburg et al. ('695) who teaches wherein microwells of a microtiter plate can be coated by vapor deposition to enhance the performance of the microtiter plate (Col 8, lines 30-42).

Regarding Claim 213, Kim et al., Bochner et al. and Alberte et al. do not disclose wherein the of said precursor material is a vapor of para-xylylene molecules or derivatives thereof and the layer comprises the polymerized para-xylylene molecules, or derivatives thereof.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a suitable precursor material, since it has been held to be within the

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general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LYDIA EDWARDS whose telephone number is (571)270-3242. The examiner can normally be reached on Mon-Thur 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571.272.1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LYDIA EDWARDS/

Examiner

Art Unit 1774

LE

/Walter D. Griffin/

Supervisory Patent Examiner, Art Unit 1774